REMARKS

Office Action

The Office notes that sequence identifiers are missing from the either the Brief Description or the legend of Fig. 2. Figures 15-16 and 4-8 were objected to on the grounds that select information cannot be read. Claims 1-7 and 9-10 were rejected under 35 U.S.C. § 112, first paragraph. Claims 1-2, 6-7, and 9-10 were rejected under 35 U.S.C. § 102. Claims 1-7 and 9 were rejected under 35 U.S.C. § 103(a). Each of these issues is addressed below.

Figure 2 Sequence Identifier

As requested by the Office, Applicants have amended the Brief Description of Figure 2 to include the appropriate sequence identifier (i.e., SEQ ID NO:1).

Figures 15-16

Figures 15 and 16 were objected to under 37 C.F.R. § 1.83(a). Applicants respectfully disagree with the Examiner's assertion that these Figures do not comply with the rule. Figures 15 and 16 are not sequence listings. Furthermore, Figures 15 and 16 do not appear in applicants' specification. Rather, each depicts a promoter fragment. Accordingly, Applicants' specification is in compliance with 37 C.F.R. § 1.83(a), and this objection should therefore be withdrawn.

Figures 4-8 and 21

Figures 4-8 and 21 were objected to as including information that cannot be read. To address the readability issue of Figures 4-8, replacement figures are enclosed. In addition, a color drawing of Figure 21 is submitted in accordance with 37 C.F.R. § 1.84(a)(2). Applicants respectfully request that these objections be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-7 and 9-10 were also rejected as failing to comply with the enablement and written description requirements. Applicants respectfully disagree.

As an initial matter, Applicants point out that, with respect to claim 7, there can be no question that the enablement and written description requirements are satisfied, as MKK4 is presented in Applicants' specification.

With respect to the remaining claims, the rejection turns on the assertion that the specification fails to provide guidance for a method of enhancing pathogen resistance in a plant by transformation with a nucleic acid encoding any MAPKK kinase domain. This rejection should be withdrawn.

All of the tools for expressing MAPKK DNA molecules were known when applicant filed the patent application. Exemplary expression vectors, promoters, and terminators are described in the specification, for example, at pages 33-44. Plants expressing MAPKK genes are then be selected, for example, as described in Example 14. Given these exemplary teachings and results, Applicants' specification cannot be found

as failing to enable the claimed invention when the techniques required to practice the invention are disclosed in the specification and available to those skilled in the art. See *In re Wands, 858 F.2d* 731, 740, 8 USPQ2d 1400, 1406; *In re Strahilevitz*, 668 F.2d 1229,1232, 212 U.S.P.Q. 561, 563 (C.C.P.A. 1982).

Applicants also direct the Office's attention to the enablement standard as articulated in *In re Wands,* 858 F.2d. 713, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). *Wands* involved the identification of monoclonal antibodies of a specific isotype directed against particular antigens. The nature of this technology involved screening hybridomas to identify those that secreted antibody having the desired characteristics. Identifying crucifer plants having the desired characteristics according to the present invention, as in *Wands,* involves straightforward and routine screening methods. As was stated in *Wands*, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Certainly, in Applicants' case, identifying crucifer plants having the desired disease resistance cannot constitute undue experimentation. Moreover, it is improper to find that such experimentation is "undue" simply because it requires some "trial and error," *W.L. Gore & Assoc. v. Garlock, Inc.* 721 F.2d 1540, 1557, 220 U.S.P.Q. 303, 316 (Fed. Cir. 1983). This is true even when the experimentation is needed to weed out inoperative embodiments. *Atlas Powder v. E.I. DuPont deNemours*, 750 F.2d 1569, 1576-77, 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984). For the all of the above-mentioned reasons, Applicants respectfully request

withdrawal of § 112 rejection on the grounds that Applicants' specification fails to enable the claims as amended.

In connection with the written description rejection as applied to MAPKKs, in general, Applicants note that, the Federal Circuit, in *Falkner v. Inglis*, 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. May 26, 2006) has stated:

> [I]t is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. See Capon, 418 F.3d at 1357 ("None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., Regents v. Lilly, Fiers v. Revel, Amgen, or Enzo Biochem, require a redescription of what was already known."). Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." Id. at 1358. Rather, we explained that:
>
> > The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

The court further stated (emphasis added):

> Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.

> **Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference [note omitted] (where permitted) of such genes and sequences.**

Applicants submit that the present specification provides a written description of the presently claimed invention in sufficient detail to satisfy the standard set by the Federal Circuit in *Falkner,* 448 F.3d 1357, 79 USPQ2d 1001. Like the situation in *Falkner*, where the written description of a genus of poxvirus DNA was supported by mentioning vaccinia virus, a poxvirus, Applicants' disclosure of various MAPKKs supports the written description of the genera included in the present claims.[1] This basis of the § 112 rejection should therefore be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1-2, 6, and 9-10 were rejected under 35 U.S.C. § 102(a) as anticipated by Yang. Claims 1-2, 6-7, 9, and 10 were rejected under 35. U.S.C. § 102(e) as anticipated by Xing.

Claim 1, as amended, incorporates the limitation of claim 3 and these rejections should therefore be withdrawn. Applicants note that the present amendment was made to advance prosecution, and reserve the right to pursue any canceled subject matter in this or a continuing application.

[1] Appellant notes that in *Falkner* the specification of prevailing party Inglis provided "a detailed example of an embodiment that comprised not a poxvirus, but a herpesvirus, including the identity of the deleted essential sequences therein." Falkner 448 F.3d 1364-65, 79 USPQ2d 1001, 1006.

Rejection under 35 U.S.C. § 103(a)

Claims 1-7 and 9-10 were rejected under 35. U.S.C. § 103(a) as obvious in view of Xing. For the following reasons, this rejection should be withdrawn.

The Office asserts that

> [o]ne of ordinary skill in the art would have been motivated to transform the plants with a nucleic acid encoding MKK4 because of the suggestion of Xing et al. to do so (column 6 [sic], lines 41-51). One of ordinary skill in the art would have been motivated to make pathogen resistant crucifers or monocots because of the economic importance of various crucifers and monocots, and because of the importance of Arabidopsis as an experimental organism.

This rejection as applied to the amended claims should be withdrawn.

Applicants, on the issue of motivation, point out that the Office cannot provide by "the level of skill in the art" what is clearly missing from the Xing reference. Xing, as acknowledged by the Office, makes no mention of cruciferous plants. Applicants direct the Office's attention to the recent Federal Circuit decision in *In re Sang Su Lee*, 277 F.3d 1338, 1342 (Fed. Circ. 2002), which shares facts with the present case. The invention claimed by Lee encompassed a method of automatically displaying the functions of a video display device and demonstrating how to select and adjust the function in order to facilitate response by the user. Both the Office and the Board of Patent Appeals and Interferences stated that the invention was obvious in view of the prior art given that "the demonstration mode is just a programmable feature which can be used in many device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation would be that the automatic demonstration mode is user friendly

and it functions as a tutorial." The Federal Circuit, in reversing this decision and holding that the claimed invention was not obvious in view of the prior art, noted that such reasoning was flawed, stating (emphasis added):

> This factual question of motivation is material to patentability, and *could not be resolved on subjective belief and unknown authority.* It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." W. L. Gore v. Garlock, Inc., 721 F.2d. 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion... *[t]he "common knowledge and common sense" on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation.* This court explained in Zurko, 258 F.3d at 1385, 59 UPQ2d at 1697, that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.'... "*Common knowledge and common sense," even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.*"

Similar to the situation in *Lee*, in applying the present rejection, the Office has relied on purported "common knowledge" in drawing motivation solely from the "level of skill in the art." As clearly indicated by the Federal Circuit in *Lee*, this approach is in error. Accordingly, Applicants submit that the presently claimed invention cannot be obvious over Xing.

CONCLUSION

Applicants submit that the claims are now in condition for allowance, and such action is hereby respectfully requested.

Enclosed is a Petition to extend the period for replying to the for two (3) months, to and including February 23, 2007, and a check in payment of the required extension fee.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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